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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/797,350	03/10/2004	Christine Moore	3300/3 US	4279

7590 03/30/2005
Pfizer, Inc.
P. O. Box 1027
Chesterfield, MO 63006

EXAMINER

ZUCKER, PAUL A

ART UNIT PAPER NUMBER

1621

DATE MAILED: 03/30/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/797,350

Applicant(s)

MOORE, CHRISTINE

Examiner

Paul A. Zucker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/14/2004</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Specification

1. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 7 recites the limitation "the cationic counterion is a mineral acid" in line 1. An acid is a charged balanced compound and cannot serve as a counterion. Claim 7 is therefore rendered indefinite.
3. Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 12 and 13 recite the limitation "between zero and up to two" in line 2. Applicants appear to be attempting to claim the range between a point and a second range. It is therefore unclear between which two points the molar equivalents of cationic counter ion must lie. Claims 12 and 13 are therefore rendered indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-7, 10 and 12-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Webber et al (US 2002/0019563-A1 02-2002). Webber discloses (Paragraphs [0328]-[0330], Example 32) the mono hydrochloride salt of S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine anticipating claims 12 and 13. Webber discloses (Paragraphs [00253]-[0255], Example 20) the production of the salt-free compound (presumably zwitterionic) S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine (having 0 equivalents of hydrochloride ion) by elution through a column of anionic ion-exchange resin. Webber further discloses (Paragraphs [00322]-[0324], Example 30) the conversion of the mono hydrochloride salt of S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine to the corresponding acetate salt on a column of acidic resin. Therefore Webber anticipates claims 1-7, 10 and 12-15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Webber et al (US 2002/0019563-A1 02-2002) in view of Puetter et al (US 4,818,409 04-1989).

Instantly claimed is a method of removing counter ions from a salt compound in a solution, comprising contacting the compound in solution with an appropriate ion exchange medium, and separating the solution containing the compound from the ion exchange medium.

Webber teaches (Paragraphs [0328]-[0330], Example 32) the mono hydrochloride salt of S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine anticipating claims 12 and 13. Webber teaches (Paragraphs [00253]-[0255], Example 20) the production of the salt-free compound (presumably zwitterionic) S-[2-[(1-Iminoethyl)amino]ethyl]-2-methyl-L-cysteine (having 0 equivalents of hydrochloride ion) by elution through a column of anionic ion-exchange resin. Webber further teaches (Paragraphs [00322]-[0324], Example 30) the conversion of the mono hydrochloride salt of S-[2-[(1-

Iminoethyl)amino]ethyl]-2-methyl-L-cysteine to the corresponding acetate salt on a column of acidic resin.

The differences between the instantly claimed process and that taught by Webber are as follows:

- a. Webber teaches only the use of a column containing ion -exchange resin while the use of a stirred vessel or series of vessels is instantly claimed;
- b. Webber does not appear to contemplate the use of an ion-exchange membrane while such use is instantly claimed.

One of ordinary skill in the art, however, would have considered modifying the process of Webber by using a stirred flask containing a solution of the salt to be converted and the ion-exchange resin instead of a column of resin since such a modification would obviate the need for the liquid handling equipment required for transfer of the solution to the ion-exchange resin column and lead to reduced process cost. The use of multiple flasks would be motivated by a desire to increase the scale of the process. (The Examiner here notes that Webber teaches direct absorption of salt on resin. See, for example, Webber at paragraph [0347]). There would have been a reasonable expectation for success based on the fact that only simple, routine mechanical modifications are required.

Webber does not contemplate the use of ion-exchange membranes. Puetter, however, teaches (Abstract) the use of ion-exchange membranes for obtaining aqueous solutions of acids and bases from their salts. In particular, Puetter teaches

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(Column 2, lines 19-38) that his methods are suitable for the isolation of amino acids from their salts. Puetter further teaches (Column 2, lines 19-38) that stoichiometric amounts of resins are required in ion exchange processes which is uneconomical, leads to product losses and/or product dilution. Puetter teaches (Column 1, lines 62-63) that use of his membranes overcomes these problems.

Thus one of ordinary skill in the art would have been motivated to replace the ion-exchange columns of Webber with the membranes of Puetter in order to achieve the process advantages taught by Puetter. Because of Puetter's teaching of the suitability of his membranes for the instantly claimed purpose, there would have been a reasonable expectation for success.

Thus the instantly claimed process would have been obvious to one of ordinary skill in the art.

Conclusion

6. Claims 1-15 are pending. Claims 1-15 are rejected.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 571-272-0650. The examiner can normally be reached on Monday-Friday 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann R. Richter can be reached on 571-272-0646. The fax phone

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number for the organization where this application or proceeding is assigned is 571-272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



PAULA ZUCKER, PH.D.
PRIMARY EXAMINER